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ART UNIT	**PAPER NUMBER**
1647	14

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Please find below and/or attached an Office communication concerning this application or proceeding.

PLEC007

Office Action Summary	Application No.	Applicant(s)	
	09/817,814	JEFFERS ET AL.	
	Examin r	Art Unit	
	Jegatheesan Seharaseyon	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *1-17,21-32,34-42,44-47 and 49-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *18-20,33,43 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *7,9 &13* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's election without traverse of Group III, claims 18-20, 33, 43 and 48, drawn to antibodies in Paper No. 11 (8/22/02) is acknowledged. Claims 1-17, 21-32, 34-42, 44-47 and 49-65 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 11 (8/22/02). In addition, claims 18, 33 and 43 will be examined to the extent they read on the elected invention.

Specification

2. Applicant is reminded of the proper content of an abstract of the disclosure.

A patent abstract is a concise statement of the technical disclosure of the patent and should include that which is new in the art to which the invention pertains. If the patent is of a basic nature, the entire technical disclosure may be new in the art, and the abstract should be directed to the entire disclosure. If the patent is in the nature of an improvement in an old apparatus, process, product, or composition, the abstract should include the technical disclosure of the improvement. In certain patents, particularly those for compounds and compositions, wherein the process for making and/or the use thereof are not obvious, the abstract should set forth a process for making and/or use thereof. If the new technical disclosure involves modifications or alternatives, the abstract should mention by way of example the preferred modification or alternative.

The abstract should not refer to purported merits or speculative applications of the invention and should not compare the invention with the prior art.

Where applicable, the abstract should include the following:
(1) if a machine or apparatus, its organization and operation;
(2) if an article, its method of making;
(3) if a chemical compound, its identity and use;
(4) if a mixture, its ingredients;
(5) if a process, the steps.

Extensive mechanical and design details of apparatus should not be given.

3. The abstract of the disclosure is objected to because it uses the term "novel" and refers to speculative applications of the invention. Correction is required. See MPEP § 608.01(b).

4. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

Drawings

5. The drawings have been objected by the draftsperson (see enclosed PTO 948).

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

1. Correction of Informalities -- 37 CFR 1.85

New corrected drawings must be filed with the changes incorporated therein. Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and centered within the top margin. If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings **MUST** be filed within the **THREE MONTH** shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

2. Corrections other than Informalities Noted by Draftsperson on form PTO-948.

All changes to the drawings, other than informalities noted by the Draftsperson, **MUST** be made in the same manner as above except that, normally, a highlighted (preferably red ink) sketch of the changes to be incorporated into the new drawings **MUST** be approved by the examiner before the application will be allowed. No changes will be permitted to be made, other than correction of informalities, unless the examiner has approved the proposed changes.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.185(a). Failure to take corrective action within the set (or extended) period will result in **ABANDONMENT** of the application.

Claim Objections

6. Claim 18 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Applicant should note the "Infringement Test" for dependent claims in MPEP § 608.01(n). The test for a proper dependent claim is whether the dependent claim includes every limitation of the parent claim. A proper dependent claim shall not conceivably be infringed by anything which would not also infringe the base claim. In the instant case, the antibody claims could be infringed without infringing the claim from which it depends, i.e. the protein claim. Therefore, they are improperly dependent and should be rewritten in independent form.

7. Claim 33 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 31 fails to place any limitation on the base claim 26. Furthermore, claim 26 is trying to identify an agent functionally without any structural attribute. Therefore, they are improperly dependent and should be rewritten in independent form.

Claim Rejections - 35 USC § 101

9. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 18-20, 33, 43 and 48 are rejected under 35 U.S.C. 101 because the claimed invention is drawn to an invention with no apparent or disclosed specific and substantial credible utility. The instant application has provided a description of an isolated DNA encoding a protein and the protein encoded thereby. The instant application does not disclose the biological role of the nucleic acid, the encoded protein or the antibody that immunospecifically binds to the polypeptide or the significance these either.

It is clear from the instant specification that the "FGF-CX" protein (SEQ ID NO:2) described therein is what is termed an "orphan protein" in the art. This is a protein whose cDNA has been isolated because of its similarity to known proteins. There is little doubt that, after complete characterization, this protein, the antibody binding to the protein, and the nucleic acid encoding it, may be found to have a specific and substantial credible utility. This further characterization, however, is part of the act of invention and until it has been undertaken, Applicant's claimed invention is incomplete. The instant situation is directly analogous to that which was addressed in *Brenner v. Manson*, 148 U.S.P.Q. 689 (Sus. Ct, 1966), in which a novel compound which was structurally analogous to other compounds which were known to possess anti-cancer activity was alleged to be potentially useful as an anti-tumor agent in the absence of evidence supporting this utility. The court expressed the opinion that all chemical compounds are "useful" to the chemical arts when this term is given its broadest interpretation. However, the court held that this broad interpretation was not the intended definition of "useful" as it appears in 35 U.S.C. §101, which requires that an

invention must have either an immediately obvious or fully disclosed "real world" utility. The court held that:

> "The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility", "[u]nless and until a process is refined and developed to this point-where specific benefit exists in currently available form-there is insufficient justification for permitting an applicant to engross what may prove to be a broad field", and "a patent is not a hunting license", "[i]t is not a reward for the search, but compensation for its successful conclusion."

The instant claims are drawn to an antibody immunospecifically binds a protein of as yet undetermined function or biological significance. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that the "FGF-CX" protein or the antibody binding to the "FGF-CX" polypeptide of the instant application could be used in a method of diagnosing, treating, preventing, or delaying a tissue proliferation-associated disorder, such as "tumors, restenosis, psoriasis, Dupuytren's contracture, diabetic complications, Kaposi sarcoma, and rheumatoid arthritis" (see page 6, lines 9-13 of the specification), in a method of "treating a pathological state in a mammal" by administering the polypeptide (see page 5, line 14), in a method of "promoting growth of cells in a subject" wherein the cells are "in the vicinity of a wound, cells in the vascular system, cells involved in hematopoiesis, cells involved in erythropoiesis, cells in the lining of the gastrointestinal tract, and cells in hair follicles" (see page 5, lines 24-27), in "methods of diagnosing the presence or amounts of these compositions, in screening for and identifying therapeutic agents related to FGF-

CX-associated pathologies, and in methods of treatment of various kinds of malignancy" (see sentence spanning pages 18-19), for use in screening assays, detection assays, predictive medicine, and methods of treatment (see sentence spanning pages 68-69), for stimulation of fibroblasts for use in wound healing (see page 77, lines 29-30), for stimulation of hematopoietic cells, immune system cells, and vascular smooth muscle cells, as well as for treating bone fractures and osteoporosis (see page 78, lines 1-3), diagnosis of cerebral tumors (page 78, lines 3-4), and for treatment of cancer (page 78, lines 9-13). Neither the specification nor the prior art demonstrates a causal correlation or nexus of the claimed polypeptide with any of the plethora of conditions or disorders contemplated by the instant specification, therefore, there is no evidence of record that would provide for a method of treating/diagnosing any of the listed conditions or disorders. There is absolutely no evidence of record or any line of reasoning that would support a conclusion that the "FGF-CX" protein of the instant application is involved in regulating growth and/or differentiation of any *particular* cell population. The record fails to indicate any evidence of any of these biological activities, and it would appear that until some actual and specific significance can be attributed to the protein identified in the specification as FGF-CX, the gene encoding it, or the antibody that binds it, the instant invention is incomplete. The instant specification refers to "FGF-CX - like activities and physiological functions", but fails to describe what these activities or functions are. The specification asserts that the claimed protein will have activities similar

to other FGF proteins based on amino acid sequence similarity, but it is not clear or predictive which activity of the FGF family will be possessed by the claimed protein based on structural similarity alone. The protein of the instant specification is a compound which is known to share some structural similarity to the FGF family of proteins which are known in the art to have biological significance in regulation of cell proliferation, differentiation, and function based on sequence similarity to members of the FGF-family. However, as indicated in Galzie et al. (Biochem. Cell Biol. 75: 669-685, 1997), the FGF family is complex and diverse (see abstract). Table 1 of Galzie et al. details the biological significance of the first 9 members of this protein family, wherein none of the associated functions are found in common with any other family member. In the absence of a knowledge of the biological significance of "FGF-CX", there is no immediately obvious patentable use for it or the receptor which binds it. The disclosed protein only shares approximately 70% amino acid sequence similarity/identity with the most closely related protein of the prior art (FGF-9, see page 15, lines 23-25). Based on this degree of sequence similarity, it is unlikely and unpredictable if any one biological activity of the prior art will be possessed by the claimed protein. Furthermore, the prior art of record demonstrates that the biological function of the protein family to which the disclosed protein is said to be a member is so diverse, that one could not predict which biological activity is possessed by the disclosed protein based on structural similarity alone, especially since all the members share structural similarity, but not functional

similarity. To employ the instant invention in any of the disclosed methods would clearly be using it as the object of further research that has been determined by the courts to be a utility which, alone, does not support patentability. Since the instant specification does not disclose a credible "real world" use for the claimed invention, it is incomplete and, therefore, does not meet the requirements of 35 U.S.C. §101 as being useful.

The instant specification provides data on expression of the claimed protein, indicating that it is expressed in normal cerebellum, as well as in several human tumor cell lines without being expressed in corresponding normal tissues. The specification provides a chromosomal location for the FGF-CX and "[e]xpression of heterologous FGF-CX in NIH 3T3 cells is found to induce their transformation and tumorigenicity" (see page 18, lines 15-16). The specification also shows that upon injecting FGF-CX transformed NIH 3T3 cells into immunocompromised athymic nude mice tumor is produced in the animal (pages 104-105). However, these disclosed properties of the claimed protein, expression pattern, the ability to transform fibroblast cells in culture and formation of tumor in the nude mouse does not provide a specific, substantial and credible utility for the claimed polypeptides. Expression of the claimed polypeptide in cancer tissue and the formation of a tumor in the nude mouse alone do not establish a nexus between the claimed protein and cancer growth. Expression of the claimed polypeptide could just as likely be a result of the cancer, and not a causative agent, therefore one of ordinary skill in the art could not target the claimed polypeptide for treatment of the cancer. The instant specification fails to teach that the claimed

polypeptide is diagnostic for any specific cancer, as it is found in normal and diseased tissue. The instant specification teaches that administration of the polypeptide stimulates proliferation of fibroblasts in culture, but these cells also lose contact inhibition, meaning that the cells take on a transformed phenotype. Therefore, the claimed polypeptide would not be considered useful for wound healing as asserted in the specification. Page 102 of the instant specification states "[s]pecific disease indications where therapeutic targeting of FGF-CX might be applied include adenocarcinomas of the colon, prostate, lung, kidney, uterus, breast, bladder, ovary" (see lines 22-24). However, in the absence of a nexus or correlation with a particular disease or cancer, the instant specification does not disclose a credible "real world" use for the claimed invention, it is incomplete and, therefore, does not meet the requirements of 35 U.S.C. §101 as being useful.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10a. Claims 18-20, 33, 43 and 48 are rejected under 35 U.S.C. §112, first paragraph, as failing to adequately teach how to use the instant invention for those reasons given above with regard to the rejection of these claims under 35 U.S.C. §101.

10b. Claims 18-20, 33, 43 and 48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

the application was filed, had possession of the claimed invention. *This is a written description rejection.*

The Office will read the limitations of claim 1 into claim 18 for the purpose of examination. Claim 1 recites "a variant", "a mature form of an amino acid sequence", "a variant of a mature form of an amino acid sequence", "polypeptides having at least 85% sequence identity to SEQ ID NO: 2" and "fragments of the amino acid sequence".

The specification discloses FGF-CX polypeptide with amino acid sequence of SEQ ID No: 2 (Page 2, lines 11-12). This disclosure meets the written description and enablement provisions of 35 USC 112, first paragraph. However, the instant specification fails to provide adequate written description to the various polypeptides described. Since the instant claims are drawn to antibodies that bind immunospecifically to the polypeptide described above, they too lack written description. The claims as written, however, encompass various polypeptide sequences which were not originally contemplated and fail to meet the written description provision of 35 USC 112, first paragraph because the written description is not commensurate in scope with the recitation of claims 31-47. The specification does not provide written support for the genus encompassed by the instant claims.

First, the recitation of "a mature form" is directed to a very specific species that is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The structure of a "mature form" cannot be predicted on the basis of the amino acid sequence of the entire protein since the protein may be

proteolytically cleaved in vivo, as well as being differentially processed based on which in tissue the protein is expressed. The structure of the variants contemplated by the Applicant are unpredictable, because the variants could include single amino acid change or multiple amino acid changes.

Second, the specification does not provide a complete structure of those molecules which have at least 85% sequence identity to SEQ ID NO:2, or to variants of the disclosed polypeptide of SEQ ID NO:2. The claims also fail to recite other relevant identifying characteristics (physical and/or chemical and/or functional characteristics coupled with a known or disclosed correlation between function and structure) sufficient to describe the claimed invention in such full, clear, concise and exact terms that a skilled artisan would recognize applicant was in possession of the claimed invention. The claims are directed to an antibody which binds to various species of amino acid sequences, the structure of which cannot be determined or predicted from full-length amino acid sequence alone and the specification does not provide evidence of isolation or conception of the structure of the "a variant" or "a mature form of an amino acid sequence" or a "variant thereof" or "polypeptides having at least 85% sequence identity to SEQ ID NO: 2" or "fragments". Therefore, the specification does not provide adequate written description of the various amino acid sequences, and thus the claimed invention, to the extent that it reads upon various amino acid sequences is not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Vas-Cath Inc. v. Mahurkar, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (*See Vas-Cath* at page 1116).

With the exception of very particular amino acid sequences that are disclosed in the instant application, the skilled artisan cannot envision the detailed chemical structure of the encompassed polypeptide molecules and therefore conception of an antibody that binds immunospecifically to the polypeptide is not achieved until reduction to practice has occurred, regardless of the complexity or simplicity of the method of protein expression. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The specific molecular structure is required. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

One cannot describe what one has not conceived. See *Fiddes v. Baird*, 30 USPQ2d 1481, 1483. In *Fiddes v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

The instant claims are directed to a structure, which could be made, but for which, there is no written description. As in *Fiddes v. Baird*, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class because the specification provided only the bovine sequence. In the instant situation,

the specification only provides the full-length protein for antibody binding, but fails to provide a description of the "broad class" of mature forms of polypeptides, protein variants and fragments, regardless of whether they could be made or isolated. The species specifically disclosed are not representative of the genus because the genus is highly variant. As a result, it does not appear that the inventors were in possession of the various polypeptide sequences binding to the antibody set forth in claims 18-20, 33, 43 and 48.

10c. Claim 33 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

This claim depends on claim 31 that depends on claim 26. The specification describes the intention to treat a subject with aberrant FGF-CX expression or activity by administering agents that will regulate the expression (page 89, line 12-27). However, the specification does not disclose the agent contemplated for the regulation of FGF-CX expression structurally. Applicant is attempting define this agent functionally. The agents contemplated for use include nucleic acids, polypeptide or analogs and antibodies etc (Page 89, lines 19-27). The claims as written, however, encompass agents which were not originally contemplated and fail to meet the written description provision of 35 USC 112, first paragraph because the written description is not commensurate in scope with the recitation of claim 33. The specification does not provide written description for the following term: agents capable of regulating the

aberrant FGF-CX expression or activity. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed" (*See Vas-Cath* at page 1116). Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

As a result, it does not appear that the inventors were in possession of invention to use the different agents set forth in claim 33.

10d. Claims 43 and 48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 43 and 48 are directed to pharmaceutical composition comprising an antibody that binds immunospecifically to the polypeptide.

The specification teaches a composition comprising antibodies specifically binding a FGF-CX protein of the invention (pages 56-57). The specification does not teach how to use a FGF-CX antibody "pharmaceutical" composition without undue experimentation for the treatment of a disease in an animal. The specification lists disorders to be treated (page 6, lines 9-13), but there are no working examples directed

to a particular disorder in an animal or administration of the FGF-CX antibody to an animal for treatment. (Note: This issue could be overcome by deleting the word "pharmaceutical" from the claims.)

Due to the large quantity of experimentation necessary to determine the quantity of FGF-CX antibody to be administered, the most effective administration route and the duration of the treatment, the lack of direction/guidance presented in the specification regarding the same, the absence of working examples directed to the same, the complex nature of the invention, and the unpredictability of the effects of the FGF-CX antibody composition *in vivo*, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

11.The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 33 isrejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11a. Claim 33 is rejected as vague and indefinite in the recitation of the phrase "has a molecular weight not more than about 1500 Da". It is unclear which agent Applicant intends to use. Applicant is trying define the agent by its size.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

12a. Claims 18-20, 33, 43 and 48 are rejected under 35 U.S.C. 102(b) as being anticipated by Kurokawa et al. (U.S. Pat. No. 5,571,895).

The instant invention is directed to an antibody that binds immunospecifically to a polypeptide. They are also directed to pharmaceutical composition containing the antibody and kit.

Kurokawa et al. disclose and teach a polypeptide which meets the structural limitations of the instant claims in that it could be considered a "variant" of SEQ ID NO:2 (see SEQ ID NO: 3 of Kurokawa et al.) as well as being an isolated polypeptide comprising an amino acid sequence which is a fragment of the sequence of SEQ ID NO:2 (there is no size limitation on "fragment", therefore, a single amino acid in common meets this structural limitation). Kurokawa et al. describe an antibody capable of binding the polypeptide of the instant invention (see abstract). In addition the reference teaches the generation of monoclonal antibodies (see example 3, column 25-26). Pharmaceutical compositions containing the antibody are containing pharmacologically acceptable carrier is also contemplated in the reference (column 5, lines 20-35). The reference teaches the inhibition of tumor forming ability of the

transformants in nude mice by the administration of the antibody demonstrating its therapeutic effect (see example 17, columns 17-18). Therefore, the teaching of Kurokawa et al. anticipates the instant invention. Claims 20 and 48 are rejected insofar as they depend on rejected claims 18 and 43.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

13a. Claims 20 and 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kurokawa et al. (U.S. Pat. No. 5,571,895) in view of Cruse et al.(Illustrated Dict. of Immu., 1995).

The instant invention is directed to an antibody that binds immunospecifically to a polypeptide. They are also directed to pharmaceutical composition containing the antibody and kit.

The relevance of Kurokawa et al. has been set forth above. The reference does not teach humanized or human antibody. The reference also does not teach a kit containing a pharmaceutical composition. However, generating human antibodies or humanized antibodies to specific polypeptide is routine and well known in the art (see page 143 of Cruse et al.). In addition, packaging pharmaceutical compositions in a kit is also well known in the art. One of ordinary skill in the art would have been motivated to generate human antibodies or humanized antibodies to specific polypeptide for therapeutic purposes with the expectation of minimal immune response against the pharmaceutical composition. In addition, it would be packaged in a kit for the routine commercial exploitation of the invention. Thus, the claimed invention would have been *prima facie* obvious as a whole at the time it was made, especially in the absence of evidence to the contrary. Therefore, the instant invention is obvious over Kurokawa et al. (U.S. Pat. No. 5,571,895) in view of Cruse et al.(Illustrated Dict. of Immu., 1995).

14. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon whose telephone number is 703-305-1112. The examiner can normally be reached on M-F: 8:30-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 703-308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and 703-308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

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November 18, 2002

JEFFREY STUCKER
PRIMARY EXAMINER